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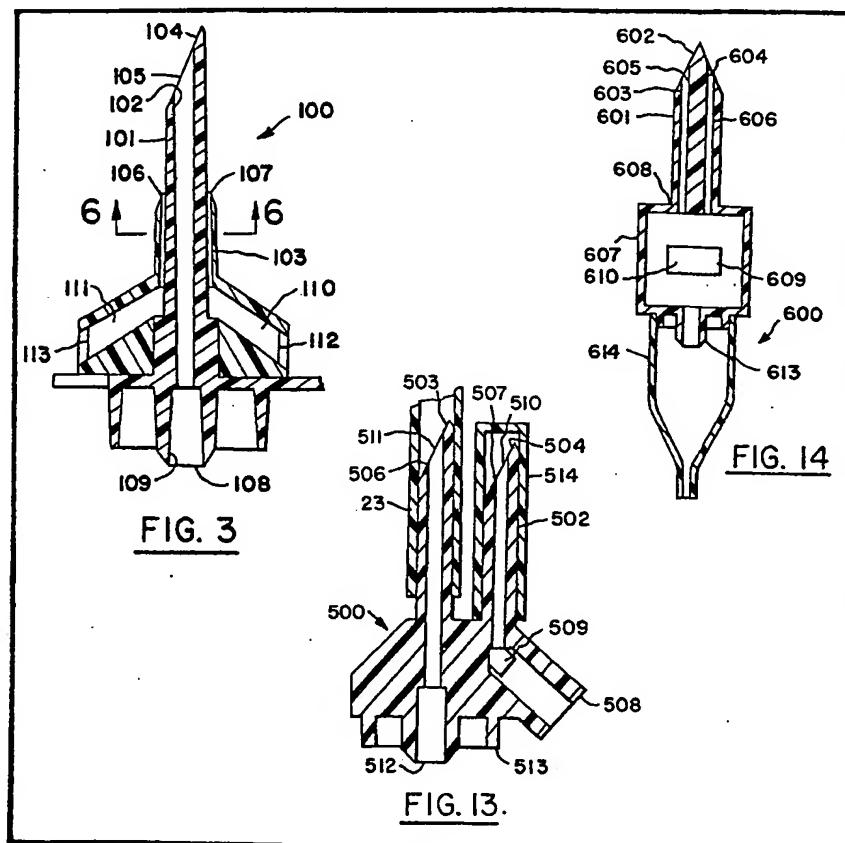
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(54) Universal piercing device

(57) A universal piercing device for vented and unvented I.V. administration sets comprises a spike 100 having ports 105, 107 for liquid and air respectively. In use, the spike is inserted sufficiently through the seal of the I.V. container to expose only port 105 for unvented systems or to expose both ports for vented systems. A hydrophobic filter 112 is used to

prevent the passage of liquid from the vent, but allow the passage of air.

In another embodiment, an air vent passage exposed to the interior of a container is blocked when the device is used in a non-vented system. In the device of Fig. 13 there are two spikes and the air vent spike is not used in a non-vented system. In a further device (Fig. 14), two passages 604, 605 open into a drip chamber 607 provided with a vent winder 609 covered by a hydrophobic filter 610.



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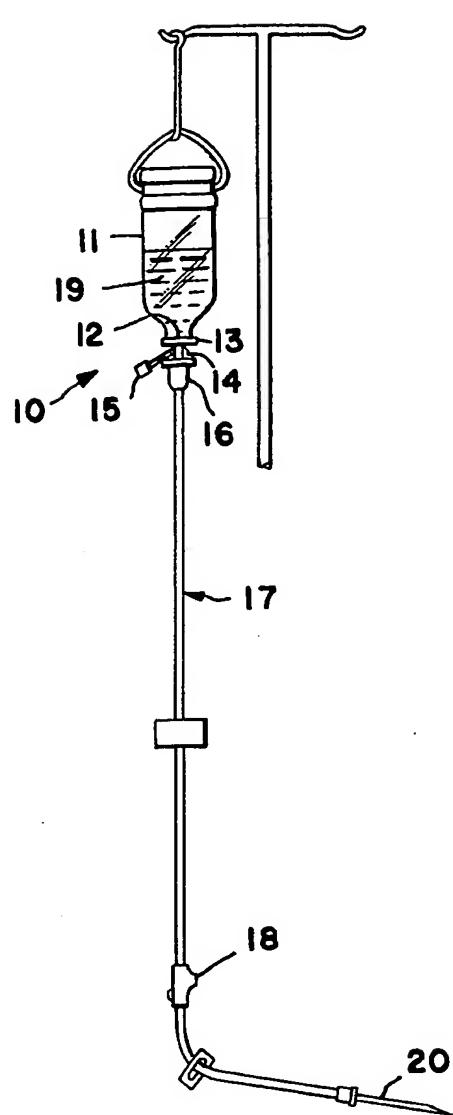


FIG. 1

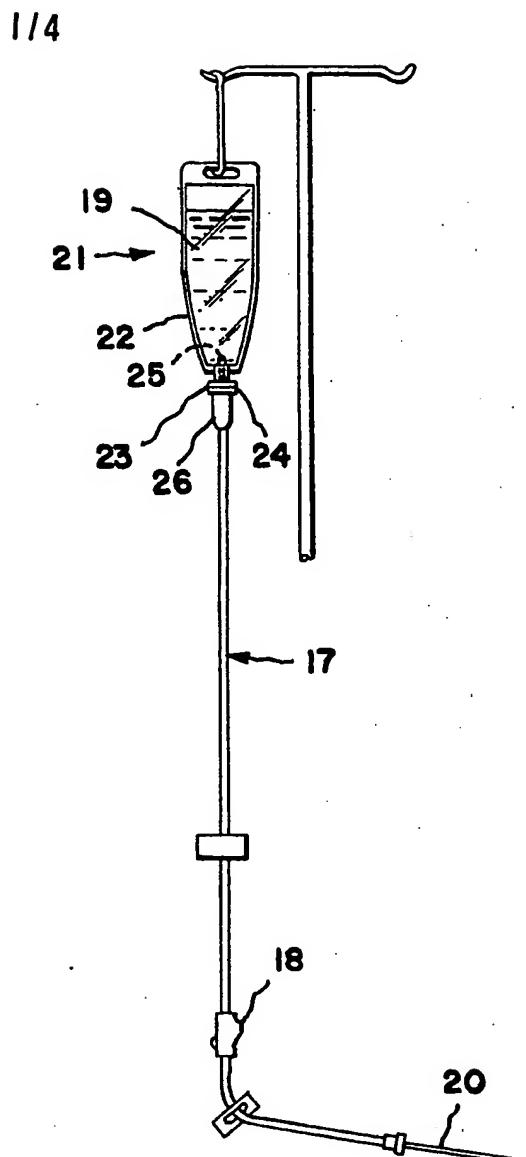
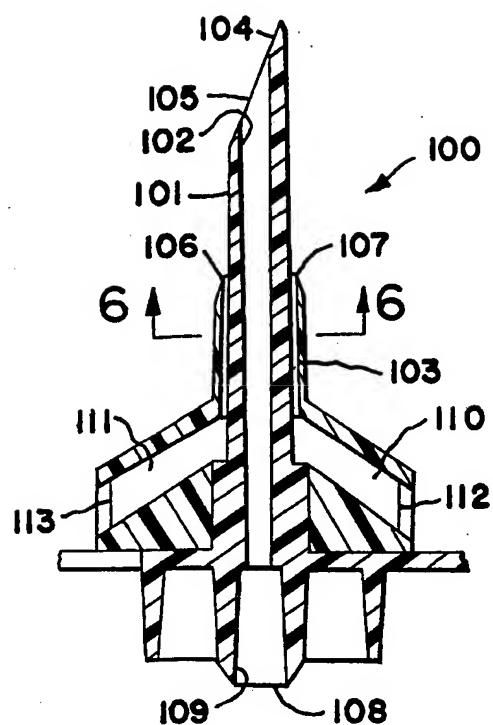
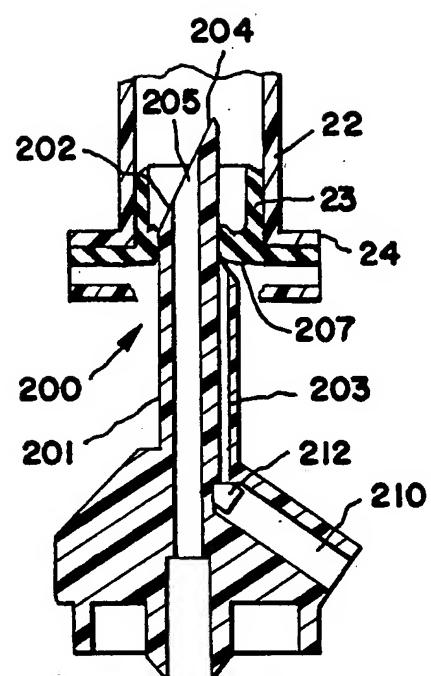
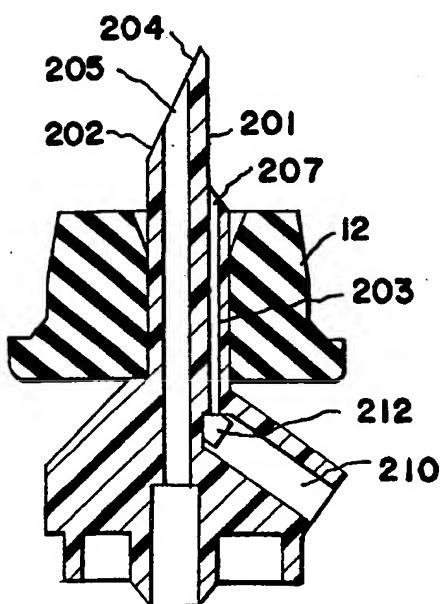
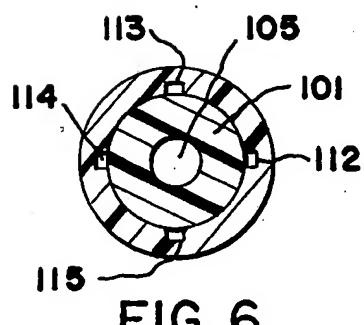
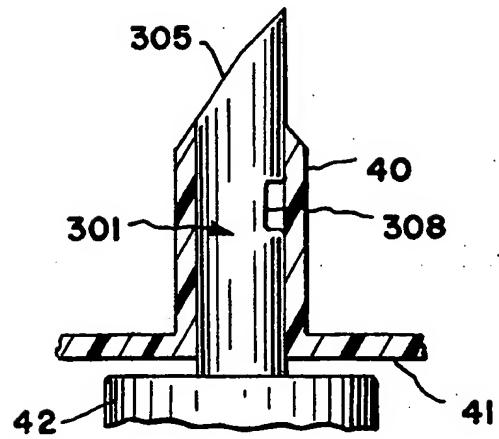
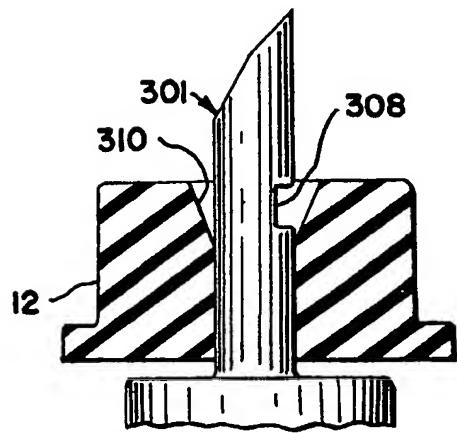
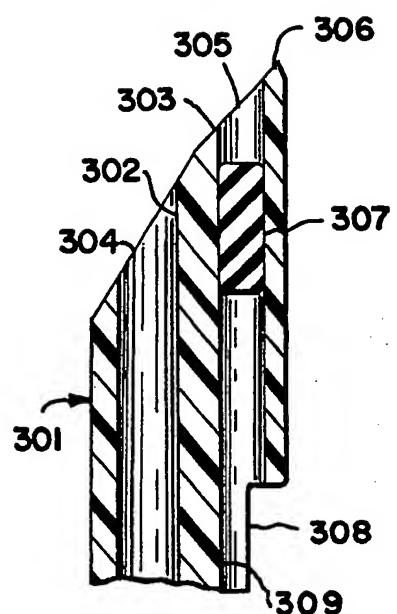
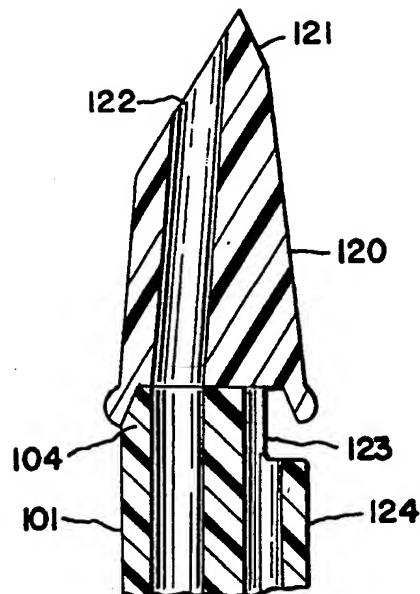


FIG. 2

FIG. 3FIG. 4FIG. 5FIG. 6

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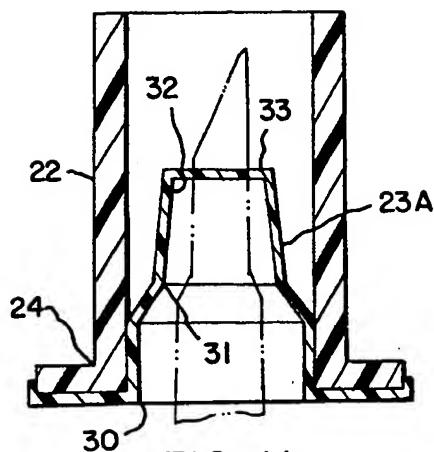


FIG. 11

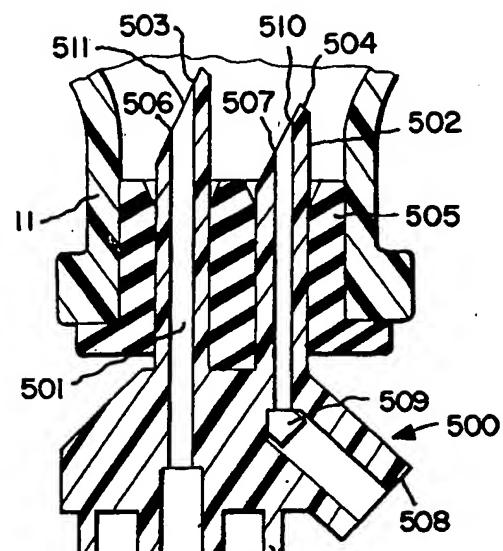


FIG. 12

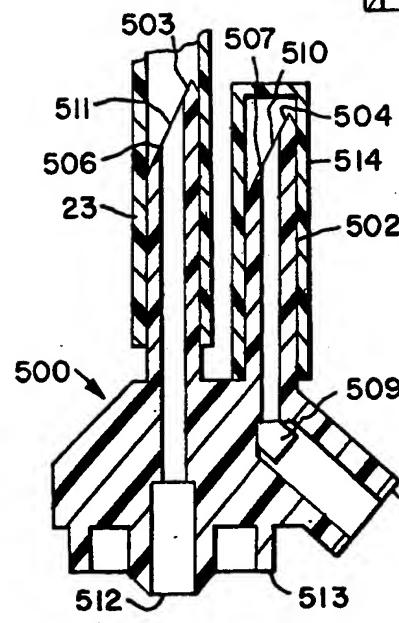


FIG. 13

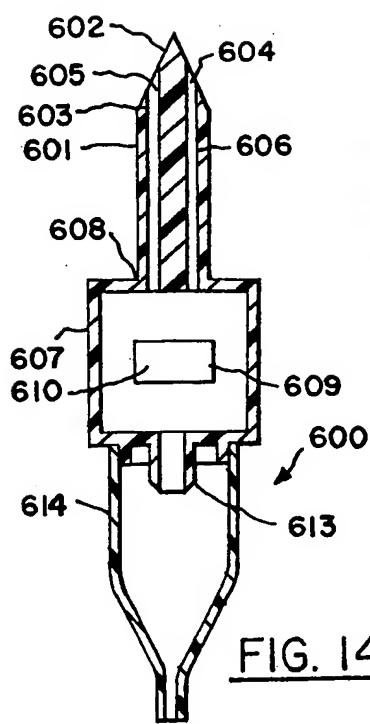


FIG. 14

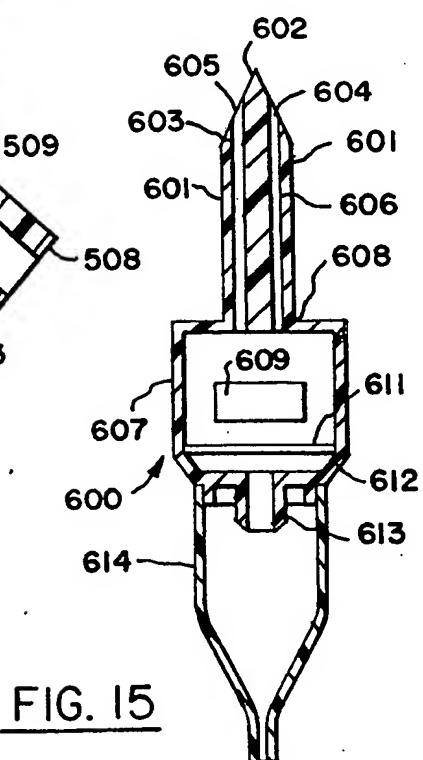


FIG. 15

SPECIFICATION
Universal piercing pin

The present invention relates to systems and equipment for the administration of medical

5 liquids to a patient, and more particularly to piercing pins usable in both vented and unvented systems for administering such liquids.

The parenteral administration of medical liquids to patients is a long established practice.

10 Liquids, including amino acids, blood, dextrose, electrolytes and saline are commonly administered to patients over prolonged periods of time. Generally, these liquids are administered from a glass bottle or plastic bag suspended 15 above the patient, containing 250 to 2000 milliliters of the liquid.

Abbott Laboratories, North Chicago, Illinois manufactures a Y-type set for the sequential administration of primary and secondary medical 20 liquids. These Veno-set® piggyback sets allow the prolonged infusion of a primary liquid to be temporarily halted by means of a back-check valve in the primary liquid flow path so as to administer a secondary liquid without the need for 25 a new veni-puncture. Similar systems are disclosed in U.S. Patents 3,886,937 Bobo, et al; and 4,105,029; Virag.

One of the problems with the above-listed systems is that in order to dispense liquids from a 30 rigid container, air must be admitted into the container as liquid is being withdrawn. Thus, each of these systems employs venting mechanisms to allow air entrance into the medical liquid container as the medical liquid is being

35 withdrawn. The conventional means of venting the container is through a vented piercing pin insertable into a puncturable closure of the medical liquid container. The piercing pin may also contain an integral drip chamber so as to 40 measure the flow of liquid by drops. Also conventionally known is an integral filtered air vent extending from the combination drip chamber and piercing pin. An example of such a piercing pin may be found in Design Patent No. D-45 229,518, "Dispensing Pin for Medical Administration Equipment" issued 12/9/73 to Albert F. Bujam and assigned to Abbott Laboratories.

In order to avoid the necessity of venting the 50 system, and to reduce costs, a recent innovation in intravenous solution administration has been the use of blow-molded collapsible containers which dispense medical liquids without the requirement of venting. An example of such 55 containers may be found in U.S. Patent No. 4,049,033, Ralston, et al.

A problem has arisen, however, in the manufacture of equipment sets in general and piercing pins in particular in that different piercing 60 pins must be used for vented and unvented systems. It has been found in fact that on some occasions, vented piercing pins have been used with unvented systems resulting in risk to air embolism to the patient. Conversely, in some

65 instances unvented piercing pins and equipment sets have been used with containers requiring venting, thereby rendering the system inoperative.

It is, therefore, an advantage of the present invention to provide a universal piercing pin which may be used in both vented and unvented systems. It is an additional advantage of the present invention to provide such a piercing pin in which the venting of the system may be selectively actuated.

70 75 According to the invention, there is provided a universal piercing pin for vented and unvented I.V. administration sets comprising a medical liquid container having a penetrable sealing member at a first end, said piercing pin comprising:—

80 a first spike member having a sharpened tip constructed and arranged for penetration of said penetrable sealing member and having associated therewith a plurality of longitudinal lumens for the passage of air or medical liquid as required;

85 a plurality of port members operatively associated with said lumens separated and positioned on said spike member for the selective admission of air into said container and liquid out of said container, said port members being angularly disposed for penetration of said penetrable sealing member.

90 In the preferred arrangement, the piercing pin 95 comprises a spike constructed and arranged for penetrating the penetrable sealing member conventionally employed in medical liquid solution containers. Incorporated in the spike are a pair of lumens extending longitudinally therethrough. The first lumen extends the length of the spike while the second lumen extends from a point proximate the middle of the device.

100 Operatively associated with the tip of the spike and with each of the lumens are a pair of ports, 105 separated on the spike, with the first port positioned proximate the tip, and the second port in the middle. As a result the spike may be inserted sufficiently into and through the penetrable sealing member to expose the first

110 port to liquid within the container without exposing the second port to liquid. Alternatively, the spike may be inserted further into the container to expose both ports to liquid. One or more hollow ducts extend from the spike and are

115 in liquid communication with the second lumen so as to permit the passage of air therethrough and into the container when desired. Either the second lumen or the duct itself may contain one or more hydrophobic membranes which seal the same and prevent the passage of liquid therethrough. At the same time the hydrophobic membranes allow the passage of air.

120 125 As an additional feature, a penetrable reseal member may be positioned within the outlet of one of the previously mentioned ducts. Such a reseal allows selected admission of medicaments into and through the duct and thereby through the lumen and into the container. The medicament may thereby be intermixed with the medical liquid

within the container before administration to the patient.

In an alternative embodiment of the invention, the previously mentioned sealing member of the medical liquid container may include a series of apertures of decreasing size arrayed in a tiered configuration and sealed at the innermost level. Another way of describing such a configuration would be a series of concentric bores of diminishing size extending axially into the reseal member. Upon insertion of the spike, the sharpened tip penetrates the innermost level of the reseal member and is exposed to the medical liquid contained within the container. However, due to the recessed configuration of the reseal, the ports designed to vent air into the container do not pass through the diaphragm, but instead are sealed by one of the tiers of the reseal. Accordingly, such a diaphragm prevents the inadvertent admission of air into an unvented system.

In an additional alternative embodiment of the invention, a conically shaped cap is attached to the distal end of the spike. Extending through the cap is a port in fluid communication with a lumen extending through the spike. The cap is pointed at its distal end and is adapted for penetrating the previously mentioned penetrable sealing member. The base of the cap is flared so as to seal the I.V. sealing member after insertion. An additional feature of the invention is a stop or flange formed about the base of the conically shaped cap for preventing the base from passing into and through the penetrable sealing member. Alternatively, the length of the port extending from the container may be designed to prevent the second port on the side of the spike from extending into the container, thereby preventing venting of the container.

Another alternative embodiment of the invention includes the use of one or more insertable plugs, adapted for insertion into one of the port members for selectively sealing same. The use of this plug prevents the passage of air into the medical liquid container in nonvented systems.

In a preferred embodiment the first port member is disposed proximate the sharpened tip of the spike. The second port member is disposed on the side of the spike. Thus the first port may be inserted into and through the penetrable sealing member while the second port remains sealed within the penetrable sealing member. If venting is required then the spike is inserted further so as to expose the second port.

In an alternative embodiment, a second spike is disposed coaxially with the first and is designed for penetration of a penetrable sealing member. Incorporated in the first and second spikes, respectively, are lumens extending longitudinally therethrough. Both spikes have ports positioned proximate their tip and in fluid communication with the respective lumens. Thus the first spike may be used to penetrate the penetrable sealing member and allow liquid to pass from the

container in a nonvented system. Both the first and second spikes may be used for allowing the passage of air and liquid into the container in vented systems.

70 In an additional embodiment of the invention the universal piercing pin comprises a first spike with a sharpened tip and a pair of lumens extending longitudinally therethrough. Two ports are disposed on the spike, the first port being proximate the tip and the second port being disposed on the side and spaced downwardly from the tip. Each port is connected to one of the lumens. A drip chamber is attached to and extends from the proximal end of the spike. The two lumens open into the drip chamber. Incorporated in the wall of the drip chamber is a vent window covered by a hydrophobic filter. The hydrophobic filter permits the passage of air into the drip chamber. When the spike is inserted sufficiently through the penetrable sealing member of the medical liquid container so that both ports are within the container, air passes into the drip chamber and up through one of the lumens and into the container. This is the mode of 90 operation used in vented systems. When an unvented system is used the spike is inserted only far enough so the port proximate the tip is positioned within the container, thereby allowing liquid to flow down through one lumen and into 95 the drip chamber. It is also preferred that a hydrophilic filter be disposed within the drip chamber, so as to prevent the passage of air into the remainder of the I.V. administration set, and into the patient. Thus, the risk of air embolism is 100 prevented.

Arrangements according to the invention will now be described by way of example with reference to the accompanying drawings in which:—

105 Figure 1 of the drawings is a front view of a vented I.V. administration set.
 Figure 2 of the drawings is a front view of an unvented I.V. administration set.
 Figure 3 of the drawings is a vertical section of 110 an improved universal piercing pin.
 Figure 4 of the drawings is a vertical section of an alternative embodiment of the universal piercing pin of Figure 3 in the port of an unvented container.
 115 Figure 5 of the drawings is a vertical section of an additional alternative embodiment of the universal piercing pin of Figure 3 in the port of a vented container.

120 Figure 6 of the drawings is a cross-sectional view taken along line 6—6 of the universal piercing pin of Figure 3.

Figure 7 of the drawings is a vertical section of a portion of the universal piercing pin of Figure 3 showing in particular an alternative tip 125 configuration comprising a conically shaped cap member affixed to the tip of the pin.
 Figure 8 of the drawings is a vertical section of a portion of the universal piercing pin of Figure 3 showing in particular a side opening port to one of 130 the lumens extending through the piercing pin,

and a resilient rubber plug inserted into the port proximate the tip of the piercing pin.

Figure 9 of the drawings is a side view, partially broken away, of the universal piercing pin of

5 Figure 3 inserted into the administrative port of a vented medical liquid container.

Figure 10 of the drawings is a side view, partially broken away, of a port for an unvented medical liquid container adapted for use with the

10 universal piercing pin of Figure 3.

Figure 11 of the drawings is a side view, partially broken away, of an alternative embodiment of, or a port for an unvented medical liquid container.

15 Figure 12 of the drawings is an alternative embodiment of the universal piercing pin of Figure 3 showing in particular a first and second spike member extending from the device through a specially adapted rubber stopper contained

20 within a medical liquid container.

Figure 13 of the drawings is a vertical section of the double-spike universal piercing pin of Figure 12 showing in particular a protective sheath affixed about the second spike, and the

25 first spike inserted into the port of an unvented medical liquid container.

Figure 14 of the drawings is an alternative embodiment of the universal piercing pin of Figure 3 showing in particular a drip chamber

30 affixed to the proximal end of the piercing pin and a vent window containing a hydrophobic membrane in the side of the drip chamber.

Figure 15 of the drawings is an alternative embodiment of the combined universal piercing

35 pin and drip chamber of Figure 14 showing in particular a hydrophilic membrane disposed within the drip chamber across the proximal end thereof.

While this invention is susceptible of

40 embodiment in many different forms, there is shown in the drawings and will herein be described in detail several specific embodiments with the understanding that the embodiments illustrated are an exemplification of the principles

45 of the invention, and are not intended to limit the invention to the embodiment illustrated.

As best seen in Figure 1 of the drawings, vented I.V. administration set 10 comprises a medical liquid container 11 having a resilient

50 resealable, penetrable sealing member 12 at first end 13. Extending through resilient penetrable sealing member 12 is a piercing pin 14, which in this case has a side vent 15 and a drip chamber 16 attached thereto. Extending from drip chamber

55 16 is a length of flexible tubing 17, upon which is affixed a flow control device 18, (in this case a roller clamp), for controlling the flow of medical liquid 19 from container 11. At the opposite end of flexible tubing 17 is a hypodermic needle 20,

60 which is inserted into the arm of a patient for administration of medical liquid 19. In operation, as medical liquid 19 exits container 11, air is drawn in through vent 15 and up into container 11 displacing the liquid that has been removed.

65 As best seen in Figure 2 of the drawings,

unvented I.V. administration system 21 comprises a collapsible medical liquid container 22 having a resilient rubber reseal 23 affixed at first end 24. Extending through resilient rubber reseal 23 is a conventional piercing pin 25 having a lumen running therethrough. Extending from piercing pin 25 is a drip chamber 26 which may be used to count the number of drops per minute and thereby determine the rate of flow of medical

70 liquid 19 from container 22. Extending from drip chamber 26 is a length of flexible tubing 17, a roller clamp 18 and a hypodermic syringe 20 at the opposite end.

In order to alleviate the requirement for

75 separate unvented or vented piercing pins as seen in Figures 1 and 2, the present invention comprises, as seen in Figure 3, an improved universal piercing pin 100, adapted for use in either vented I.V. administration system 10 or

80 unvented I.V. administration system 21. Universal piercing pin 100 as seen in Figure 3, comprises a first spike member 101 having a sharpened tip 102 constructed and arranged for penetration of penetrable sealing member 12 or 23 (Figures 1

85 and 2). Extending longitudinally through first spike member 101 is lumen 102 and disposed on spike 101 is lumen 103. Lumens 102 and 103 are adapted for the passage of air or medical liquid as required. Positioned at the distal end 104 of spike

90 member 101 is port member 105 opening into and thereby operatively associated with lumen 102. Similarly positioned at the distal end 106 of lumen 103 is port 107. When universal piercing pin 100 is to be used in unvented system 21,

95 spike member 101 is inserted sufficiently through sealing member 23 so as to expose port 105 to medical liquid 19 contained within container 22. This allows medical liquid to pass through lumen 102 and out the proximal end 108 of universal

100 piercing pin 100 through exit port 109. When universal piercing pin 100 is to be used with vented I.V. administration system 10, spike member 101 is inserted sufficiently through resilient sealing member 12 so as to expose both

105 ports 105 and 107 to medical liquid 19. Extending from duct 103 are a plurality of hollow ducts such as ducts 110 and 111 which are constructed and arranged for the passage of air therethrough and into lumen 103. By means of

110 ducts 110 and 111 air may be passed into container 23.

In order to prevent medical liquid 19 from

115 passing through lumen 103 and out of ducts 110 and 111, they must be sealed in some manner. In a preferred embodiment, at least one of the ducts 110 and 111 contains a hydrophobic membrane 112 which prevents the passage of medical liquid 19 of the lumen 103. At the same time, due to its hydrophobic properties, air may pass through

120 hydrophobic membrane 112 into and through duct 103 and thereby into medical liquid container 22. Alternatively, in order to provide a method of adding additional medicaments to medical liquid container 22, a resilient rubber

125 reseal plug 113 may be used to seal hollow duct

130

111. When additional medicaments are required, a hypodermic syringe may be inserted through resilient rubber reseal plug 113 and injected into duct 111, thereby passing liquid through lumen 5 103 and into medical liquid container 22.

An alternative embodiment 200 of a universal piercing pin may be seen in Figure 4 of the drawings. In this embodiment spike member 201 includes lumen 202 extending therethrough, and 10 sharpened tip 204 at the distal end. However, rather than extending circumferentially around spike 201 as does lumen 103 in Figure 3, lumen 203 comprises a single bore coaxially disposed to spike 201. Hydrophobic membrane 212 is 15 disposed at the proximal end of lumen 203 opening into hollow duct 210 to allow the passage of air therethrough. Again port 205 is positioned at the distal end of spike 201. Port 207 is spaced apart from port 205 sufficiently to 20 allow use of port 205 separately from port 207 in unvented systems. Disposed at the end 24 of container 22 is resilient rubber reseal plug 23. Plug 23 is adapted for penetration of spike 201 so as to expose port 205 to medical liquid 19. At the 25 same time resilient rubber reseal plug 23 is constructed so as to prevent port 207 from being exposed to medical liquid 19, thereby preventing the venting of system 21. Alternatively, as seen in Figure 5 resilient rubber reseal plug 12 in vented system 10, is adapted for penetration of spike 201 so as to expose ports 205 and 207 to medical liquid 19, thereby venting container 11 in 30 system 10.

As best seen in Figure 6 of the drawings, spike 35 101 of Figure 1 includes port 105 opening into lumen 102. Lumen 103 includes a plurality of channels 112, 113, 114 and 115 circumscribing spike 101 and interconnected so as to form a passageway for air.

40 As best seen in Figure 7 of the drawings in an alternative embodiment of the invention rather than having a sharpened tip 104, spike 101 contains a cap member 120 which is conical in shape and is attached to the distal end 104 of spike member 101. Cap 120 is fixedly attached to spike member 101 by means of ultrasonic sealing, or adhesives. Alternatively, cap 120 may be integrally formed as a part of spike member 101. Cap member 120 has a pointed portion 121 45 at the distal end thereof adapted for penetration, as was sharpened tip 102, of penetrable sealing member 12. In addition, a cap port 122 is proximal to the distal end of cap 120 and extends therethrough for the passage of liquid when the 50 piercing pin 101 is inserted into and through a penetrable sealing member. The base portion 123 of cap 120 is flared, i.e., larger in diameter than the tip portion and is of sufficient size to inhibit, but not prevent penetration of the tip through the 55 penetrable sealing member. Additionally, the flared base portion 123 effectively seals the area about the cap portion when it is inserted through the penetrable sealing member 12. As shown in Figure 4 of the drawings, penetrable sealing 60 member 23 may be adapted to prevent the 65

passage of a flared portion such as flared portion 123 through a penetrable sealing member.

As seen in Figure 7, one means by which medical liquid container 11 may be vented is 70 through the use of a side opening port 123 coaxially disposed on spike 101 and opening into lumen 124. Spike 101 may be inserted in unvented systems sufficiently to expose port 122, or, in vented systems to expose both port 122 75 and port 123.

An alternative embodiment of piercing pin 100 may be seen in Figure 8. In this particular embodiment spike member 301 has a pair of coaxial lumens 302 and 303 extending 80 longitudinally therethrough. Lumens 302 and 303 contain ports 304 and 305 proximate the distal end 306 (sharpened tip) of spike 301. Such a parallel longitudinal configuration facilitates manufacture of the device. In order to permit both 85 vented and unvented configurations, lumen 303 contains a resilient rubber sealing plug 307 inserted into and sealing port 305. Also shown is a side opening port 308 spaced and separated from port 304 so as to allow exposure of port 304 90 or ports 304 and 308 as required. Side opening port 308 is optional in that spike member 301 may be distributed having both lumens 302 and 303 in an open configuration with sealing plug 307 provided for insertion and sealing when 95 required in unvented systems.

As best seen in Figure 9 of the drawings, penetrable sealing member 12 is adapted, by means of recess 310, to expose side opening port 308 upon insertion of spike 301. As a result, in 100 vented system 10, air is permitted to enter medical liquid container 11 during use.

As further seen in Figure 10 of the drawings, in an alternative embodiment administrative port 40 extends from a medical liquid container, such as 105 container 22, and includes a flange 41 at the proximal end thereof. At the base of spike member 301 is a corresponding circular flange 42 or platform sufficiently large to abut against flange 41 when spike 301 is inserted into 110 administrative port 40. Spike member 301 is of sufficient length to extend through administrative port 40 so as to expose port 305 to the medical liquid contained within the container 22. Side opening port 308 is sealed against the wall of 115 port 40 and therefore the passage of air into medical liquid container 22 is prevented.

As best seen in Figure 11 of the drawings, an additional feature of the invention is the use of a penetrable sealing member 23a, resiliently 120 sealing first end 24 of container 22. Sealing member 23a comprises a series of coaxial bores or apertures 30, 31 and 32 of decreasing size and arranged in a tiered configuration. Aperture 30 is the largest, aperture 31 is further within sealing 125 member 23a and is of a smaller size, and so on. Aperture 32 is further again within sealing member 23a and seals sealing member 23a at its innermost level. Upon insertion of spike member 101, sealing member 23a is of sufficient length to 130 allow sharpened tip 104 to penetrate innermost

level 33 thereby exposing port 105 to medical liquid 19. At the same time sealing member 23a is of sufficient length to prevent port 107 from penetrating layer 33, thereby preventing venting 5 of container 22.

As further seen in Figure 12 of the drawings, in an alternative embodiment, universal piercing pin 500 comprises a first spike member 501 and a second spike member 502 disposed substantially 10 coaxially to each other. First and second spike members 501 and 502 each have sharpened tips 503 and 504 are adapted for penetration of resilient penetrable sealing member 505. Spike member 501 contains a lumen 506 extending 15 therethrough for the passage of liquid from a medical liquid container such as container 11. Spike member 504 contains a lumen 507 extending therethrough and opening into hollow side duct 508. Affixed within hollow duct 508 is a 20 hydrophobic membrane 509, which prevents the passage of liquid from medical liquid container 11, but allows the passage of air into and through lumen 507 and out of port 510. Medical liquid 19 is thereby allowed to pass through port 511, 25 lumen 506 and out of exit port 512 at the base 513 of universal piercing pin 500.

Alternatively, as seen in Figure 13, first spike member 501 may be inserted into administrative port 23, which is part of unvented system 21. In 30 this case, second spike member 502 is rendered inoperative. A protective shroud or sheath 514 is also provided for sealing port 510.

In an additional alternative embodiment of the invention, universal piercing pin 600, as seen in 35 Figure 14 comprises a first spike member 601 having a sharpened tip 602 constructed and arranged for the penetration of penetrable sealing members. Incorporated in spike member 601 are lumens 603 and 604 which extend longitudinally 40 therethrough and are adapted for the passage of air or medical liquid. Port member 606 is positioned separately from port 605 (closer to the proximal end of spike 601) and opens into lumen 604. Drip chamber 607 is attached to and 45 extends from the proximal end 608 of spike member 601 and is in fluid communication with both lumens 603 and 604. Incorporated in the wall of drip chamber 607 is a vent window 609 covered with a hydrophobic filter 610. 50 Hydrophobic filter 610 permits the passage of air into drip chamber 607 but prevents the passage of liquid out of vent window 609. Thus when spike member 601 is used in a vented I.V. 55 administration system such as system 10, spike member 601 is inserted sufficiently through a penetrable sealing member 12 so that both ports 606 and 605 are exposed to medical liquid. Air passing into drip chamber 607 through vent window 609 travels upwards through lumen 604 60 out port 606 and into medical liquid container 11 as medical liquid 19 passes out of medical liquid container 11 through port 605, lumens 603 and drip chamber 607.

As further seen in Figure 15, in a preferred 65 embodiment, universal piercing pin 600 also

contains a hydrophilic membrane disposed within drip chamber 607 across the base portion 612 in proximate outlet port 613, thereby preventing inadvertent administration of air into the patient.

70 Further extending from drip chamber 600 is a second drip chamber 614 which is transparent so as to allow viewing of medical liquid 19 as it passes out of outlet port 613.

Claims

1. A universal piercing pin for vented and unvented I.V. administration sets comprising a medical liquid container having a penetrable sealing member at a first end, said piercing pin comprising;
 - 80 a first spike member having a sharpened tip constructed and arranged for penetration of said penetrable sealing member and having associated therewith a plurality of longitudinal lumens for the passage of air or medical liquid as required;
 - 85 a plurality of port members operatively associated with said lumens separated and positioned on said spike member for the selective admission of air into said container and liquid out of said container, said port members being angularly disposed for penetration of said penetrable sealing member;
 - 90 2. The piercing pin as described in Claim 1 and further comprising
 - 95 a plurality of hollow duct members extending from said spike member, said duct members being constructed and arranged for the passage of air therethrough and into one or more of said lumens; and
 - 100 a plurality of hydrophobic membranes positioned within said hollow duct members and constructed and arranged for the passage of air therethrough while preventing the passage of liquid.
 - 105 3. The piercing pin as described in Claim 1 and further comprising a reseal member positioned proximate the outlet portion of one of said hollow duct members, said reseal member being
 - 110 constructed and arranged for selective admission of medicaments into and through said duct member, said lumen, said port member and thereby into said medical liquid container whereby said medicament may be intermixed into said medical liquid before administration to a patient.
 - 115 4. The piercing pin as described in Claim 1 and further comprising
 - 120 a first port member positioned proximate the tip of said spike member, said first port member being constructed and arranged for the passage of medical liquid from said medical liquid container through one of said lumens upon insertion of said spike member into said medical liquid container, and
 - 125 a second port member disposed distally from said first port member, said second port member being constructed and arranged for the passage of air from one of said lumens

into said medical liquid container, said first and second port members being spatially arranged such that spike member may be inserted through said penetrable sealing member until said first port member is within said medical liquid container while said second port member remains outside said medical liquid container thereby allowing the flow of liquid therefrom in nonvented system or,

5 10 15 20 25 30 35 40 45 50 55 60 65

said spike member may be inserted through said penetrable sealing member until said first and second port members are positioned within said medical liquid container, thereby allowing the flow of liquid from and air into said medical liquid container.

5. The I.V. administration set of Claim 1 wherein said penetrable seal member at said first end of said medical liquid container comprises; a multiplicity of apertures of decreasing size arrayed in a tiered configuration and sealed at its innermost level so as to be, upon insertion of said spike member, operatively associated with said port members whereby a selected number of said port members may be sealed thereby preventing admission of air into said medical liquid container in unvented systems.

6. The piercing pin as described in Claim 1 and further comprising;

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a plurality of insertable plug members adapted for insertion into said port members for the selective sealing thereof, said plurality of plug members being effective to prevent the passage of air into said medical liquid container in nonvented systems.

7. The piercing pin as described in Claim 5 and further including;

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a substantially conical cap member attached to said distal end of said spike member, said cap member having a sharpened tip proximate its distal end adapted for penetration of said penetrable sealing member; and a base portion constructed and arranged for limiting the depth of insertion of said spike member into said penetrable sealing member.

8. The I.V. administration set according to Claim 7 in which said penetrable sealing member is contained within a container port, and said container port includes stop means associated therewith for preventing the passage of said flared portion of said flared cap member therethrough, whereby venting of a nonvented system is prevented.

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9. The piercing pin as described in Claim 4 wherein said first port member is disposed proximate the tip of said spike member and said second port member is disposed substantially on the side of said spike member whereby said spike member may be partially inserted through said penetrable sealing member so as to expose said first port member to said medical liquid while still sealing said second port member within said penetrable sealing member permitting use of said

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piercing pin in a nonvented system.

10. A universal piercing pin for vented and unvented I.V. administration sets comprising a medical liquid container having a penetrable sealing member at a first end, said piercing pin comprising;

a first spike member having a sharpened tip constructed and arranged for penetration of said penetrable sealing member and having a plurality of lumens extending therethrough for the passage of air or medical liquid as required;

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a plurality of port members operatively associated with said lumens for the selective admission of liquid out of said container, said port members being angularly disposed for penetration of said penetrable sealing member;

a second spike member disposed coaxially to said first spike member, constructed and arranged for penetration of said penetrable sealing member and having incorporated therein a plurality of lumens extending longitudinally therethrough,

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said second spike member further having a plurality of port members operatively associated with said lumens and positioned on said second spike member for the selective admission of air through said lumens whereby said first spike member may be inserted through said penetrable sealing member for the passage of liquid from said medical liquid container in nonvented system or;

100 105 110 115 120 125

said first and second spike members may be inserted through said penetrable sealing member for the passage of air into said medical liquid container, and the passage of liquid from said medical liquid container in vented systems.

11. A universal piercing pin for vented and unvented I.V. administration sets comprising a medical liquid container having a penetrable sealing member at a first end, said piercing pin comprising;

a first spike member having a sharpened tip constructed and arranged for the penetration of said penetrable sealing member and having incorporated therein a plurality of lumens extending longitudinally therethrough for the passage of air or medical liquid as required,

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a plurality of port members operatively associated and in fluid communication with said lumens separated and positioned on said spike member for the selective admission of air into said container and liquid out of said container as desired, and a drip chamber attached to and extending from the proximal end of said spike member, said drip chamber being in fluid communication with said lumens for the passage of liquid therethrough, and having incorporated therein a vent window covered by a hydrophobic filter, said hydrophobic filter

permitting the passage of air into said drip chamber and through one of said lumens and into said medical liquid container, when two or more of said ports are positioned within said medical liquid container.

5 12. The universal piercing pin as described in Claim 1 and further comprising; a hydrophilic membrane disposed within said drip chamber across the base portion thereof proximate the drip chamber outlet port constructed and arranged to prevent the passage of air from said drip chamber and thereby through the remainder of said I.V. administration set and to the patient.

10 13. A universal piercing pin for vented and unvented I.V. administration sets comprising a medical liquid container having a penetrable sealing member at a first end, said piercing pin comprising;

15 a first spike member having a sharpened tip constructed and arranged for penetration of said penetrable sealing member and having associated therewith a plurality of longitudinal lumens for the passage of air or medical liquids as required;

20 a plurality of port members operatively associated with said lumens, and positioned on said spike member for the passage of air into said container and liquid out of said container,

25 said port members being angularly disposed for penetration of said penetrable sealing member, and

30 an insertable plug member adapted for insertion into one of said port members for

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the selected sealing thereof, said plug member being effective to prevent the passage of air into said medical liquid container in non-vented systems.

40 14. An I.V. administration set comprising; a medical liquid container having a penetrable sealing member disposed within a port extending from a first end thereof; a piercing pin comprising;

45 a first spike member having a sharpened tip constructed and arranged for penetration of said penetrable sealing member and having associated therewith a plurality of longitudinal lumens for the passage of air or medical liquids as required; and

50 a plurality of port members operatively associated with said lumens, and positioned on said spike member for the passage of air into said container and liquid out of said container,

55 said port member being angularly disposed for penetration of said penetrable sealing member;

60 said penetrable sealing member further including a series of progressive coaxial concentric bores, therethrough sealed at their innermost level and arranged for the selective sealing of one or more of said ports disposed on said piercing pin whereby said container may be vented or remain unvented, as required.

65 15. A piercing pin substantially as described with reference to Figures 3 and 6 to 10, or Figure 4, or Figure 5, or Figures 12 and 13, or Figures 14 and 15, of the accompanying drawings.

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